

09/700177
Rec'd PCT/PTO

09/700177

04 APR 2001

Attorney's Docket No. 005300-626

#9

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of) Box PCT
ÅKE LINDAHL et al.)
) Attention: DO/EO/US
Application No.: 09/700,177)
) Group Art Unit: (unassigned)
Filed: November 13, 2000)
) Examiner: (unassigned)
For: BIOLOGICALLY ACTIVE)
COMPOSITION)

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

In accordance with the duty of disclosure as set forth in 37 C.F.R. § 1.56,

Applicants submit information in conformance with 37 C.F.R. §§ 1.97 and 1.98.

Copies of the following items are provided:

- (1) "Enhancement of Percutaneous Absorption
by the Use of Volatile: Nonvolatile
Systems in Vehicles", M.F. Coldman et al.,
J. Pharm. Sci., 58, No. 9, Pages 1098 to
1102 (1969)
[Discussed at Page 5 of Specification.]
- (2) "Polymer Films From Aqueous Latex Dispersions
as Carriers for Transdermal Delivery of
Lipophilic Drugs", Proceed. 15th Intern.
Symp. Control Rel. Bioact. Material,
Abstract No. 89, Pages 147 and 148, Basel (1998)
[Discussed at Page 5 of Specification.]
- (3) East German Patent No. 217, 989
Applicant: Ernst Moritz Arnd et al.
Date: January 30, 1985.
[Discussed at Page 5 of Specification.]

- (4) "Preparation and Dissolution Characteristics of Several Fast-Release Solid Dispersions of Griseofulvin", W.L. Chiou et al., J. Pharm. Sci., Vol. 58, No. 12, Pages 1505 to 1510 (1969).
[Discussed at Page 5 of Specification.]
- (5) "Pharmaceutical Applications of Solid Dispersion Systems", W.L. Chiou et al., J. Pharm. Sci., Vol. 60, No. 9, Pages 1281 to 1301 (1971).
[Discussed at Page 5 of Specification.]
- (6) "Polymer Films From Aqueous Latex Dispersions As Carriers for Enhanced Transdermal Delivery of Lipophilic Drugs - Influence of Drug-Polymer Interactions and Formulation Parameters On Release Characteristics", R. Lichtenberger et al., Conference Proceedings, IBC Technical Services Ltd. London, Pages 360 to 366 (April 1989)
- (7) "Transdermal Drug Delivery Systems" H.P. Merkle, Meth. And Find. Exp. Clin. Pharmacol., 11(3), Pages 150 to 151 (1989).
- (8) "Copolyester of Citric Acid and 1,2,6-Hexane Triol as a Matrix for Controlled Drug Release", D. Pramanick et al., J. Polymer Materials (13), Pages 173 to 178 (1996).

- (9) German Patent No. 4,400,770
Applicant: LTS Lohmann Therapie-
Systeme GmbH & Co KG
Published: February 2, 1995
[A drug contains plaster for the enhanced
effect of estradiol. The plaster
must contain an acid, such as citric
acid, as a penetration enhancer in
an amount of 0.01 to 20 percent. It is
significant that the citric acid is
unchanged and not reacted since its
activity as a penetration enhancer
is dependent on the acid form.]
- (10) European Patent Application No. 0430491
"Transdermal Delivery Device for
Estradiol and Process for
Manufacturing Said Device"
Applicant: LABORATORIES BETA S.A.
Published: June 5, 1991

For the convenience of the Examiner a form PTOL-1449 is attached that lists the
above items. Once these items are considered, it is requested that an Examiner-initialed
copy of this form be returned to the undersigned.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

By: Benton S. Duffett, Jr.
Benton S. Duffett, Jr.
Registration No. 22,030

P.O. Box 1404
Alexandria, Virginia 22313-1404
(703) 836-6620

Filed: January 29, 2001

INFORMATION DISCLOSURE CITATION

PTO-1449

ATTORNEY'S DKT NO.
003300-696APPLICATION NO.
New ApplicationAPPLICANT
Åke LINDAHL et al.FILING DATE
November 13, 2000GROUP
Unassigned

U.S. PATENT DOCUMENTS

EXAMINER'S INITIALS	PATENT NO.	DATE	NAME	CLASS	SUBCLASS	FILING DATE

FOREIGN PATENT DOCUMENTS

EXAMINER'S INITIALS	PATENT NO.	DATE	COUNTRY	CLASS	SUBCLASS	Translation	
						Yes	No
	217 989	01-1985	DD				
	44 00 770	02/1995	DE				
	0 430 491	06/1991	EPO				

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

	M.F. Coldman et al., <i>Enhancement of Percutaneous Absorption by the Use of Volatile: Nonvolatile Systems in Vehicles</i> , J. Pharm. Sci., 58, No. 9, 1969, pp. 1098-1102
	Rainer Lichtenberger et al., <i>Polymer Films From Aqueous Latex Dispersing as Carriers for Transdermal Delivery of Lipophilic Drugs</i> , 15 th Int'l. Symp. Control Rel. Bioact. Material, Abstract No. 89, 1998, pp. 147-148
	W. L. Chiou et al., <i>Preparation and Dissolution Characteristics of Several Fast-Release Solid Dispersions of Griseofulvin</i> , J. Pharm. Sci., Vol. 58, No. 12, 1969, pp. 1505-1510
	W. L. Chiou et al., <i>Pharmaceutical Applications of Solid Dispersion Systems</i> , Vol. 60, No. 9, 1971, pp. 1281-1301
	Rainer Lichtenberger et al., <i>Polymer Films From Aqueous Latex Dispersions As Carriers for Enhanced Transdermal Delivery of Lipophilic Drugs - Influence of Drug-Polymer Interactions and Formulation Parameters on Release Characteristics</i> , Conf. Proceedings, IBC Tech. Svcs. Ltd., London, 1989, pp. 360-366
	H. P. Merkle, <i>Transdermal Drug Delivery Systems</i> , Meth. and Find. Exp. Clin. Pharama. 11 (3), 1989, pp. 150-151
	D. Pramanick et al., <i>Copolyester of Citric Acid and 1,2,6-Hexane Triol as a Matrix for Controlled Drug Release</i> , J. Polymer Materials (13), 1996, pp. 173-178

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.